

1. Science based decisions are made throughout the life span of products from initial research, development and testing, through production, marketing, and consumption. These decisions require the best science to identify, evaluate, and balance product risks and benefits. It is crucial that FDA, in collaboration with product sponsors, develop a shared understanding of new science and technologies and their effect throughout a product's life span.

What actions do you propose the agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision making?

2. As the agency attempts to meet its public health responsibilities, the speed of discovery results in an avalanche of new information from government, academic, and industry scientists.

What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's lifecycle?

3. Most products in the American marketplace, especially medical ones, have two facets. On one side they benefit users and often improve lives. They are, however, rarely without risk, and their use can result in known and unknown side effects. Consumers must weigh benefits and risks before using these products, often times with incomplete information.

What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision making?

4. The agency stated in the "FDA Plan for Statutory Compliance" that inflation has eroded real assets that can be applied to meet its public health mission while Congress has increased its responsibilities.

Because the agency must allocate its limited resources to achieve the greatest impact, what actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?

5. FDAMA requires the agency to continue to meet with stakeholders on key issues. Meetings have ranged from explaining the positions of the agency on particular issues to working with sponsors on product applications. Historically, these interactions have benefited both stakeholders, through better knowledge of FDA, and the agency, by leading to positive changes in its operations.

Because the agency wants to assure that its stakeholders are aware of and participate in its modernization activities, what additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?